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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/718,388	11/24/2000	Nobutaka Yamamoto	001554	3765

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EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT PAPER NUMBER

1636

DATE MAILED: 05/20/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/718,388

Applicant(s)

YAMAMOTO ET AL.

Examiner

Konstantina Katcheves

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-10, 12-15 and 29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-10, 12-15 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 17.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-3, 5-10, 12-15 and 29 are pending in the present application. This Office action is in response to Paper No. 19, filed 24 February 2003.

Response to Amendment

The rejections of claims 1-3, 5, 7-10, 12, under 35 U.S.C. 102(b) as being anticipated by Boyce et al. (U.S. Patent No. 4,940,666) or by Rheinwald et al. (Nature Vol.265 1977) have been withdrawn for the reasons set forth below.

Claims 1-3, 5-10, 12-15 and 29 and new claim 29 stand rejected under 35 U.S.C. 103(a) as being unpatentable over either Boyce et al. or Rheinwald et al. for the reasons of record and those discussed below.

Claims 1-3, 5-10, 12-15 and 29 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for epidermal target cells, does not reasonably provide enablement for hepatic target cells.

The rejections of claims 1-3, 5-10, 12-15 and 29 under 35 U.S.C. 112, second paragraph have been withdrawn.

Response to Arguments

Claims 1-3, 5-10, 12-15 and 29 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for epidermal target cells, does not reasonably provide enablement for hepatic target cells.

Applicant argues that the specification on page 12, lines 14-15 implies that the procedures using epidermal cells or hepatic cells are similar such that one of skill in the art would be able to obtain and inoculate hepatic cells in a manner similar to epidermal cells. The examiner does not disagree with Applicant that one of skill in the art would be able to go through the physical steps of inoculating hepatic cells on a culture dish. However, what is in question is whether one may facilitate growth and proliferation of these cells in the presence of irradiated 3T3 fibroblast cells. As previously discussed, search and review of the prior art fails to indicate that fibroblast cells either living or dead can support the growth of cells other than epidermal cells such as keratinocytes. There are numerous examples in the prior art that fibroblast cells are relevant for the growth and proliferation of epidermal cells, however no indication is found in the art nor are any working examples present in the specification where fibroblast cells can support the growth of hepatic cells. Thus, the present claims stand rejected under 35 U.S.C. 112, first paragraph.

New Grounds of Rejection

Upon further consideration of the present claims, it appears more appropriate that claims 1-3, 5-10, 12-15 and new claim 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Boyce et al. or Rheinwald et al. for the reasons of record and those discussed below. Applicant's comments and arguments regarding the rejection of these claims are addressed insofar as they are relevant to the present rejection under 35 U.S.C. 103(a).

As cited in prior Office actions, Rheinwald et al. teach that keratinocytes depend on the support of fibroblasts to initiate growth and proliferation. The reference teaches that culture dishes having lethally irradiated 3T3 cells are inoculated with keratinocytes. See page 421-422.

Boyce et al. teach a method wherein fibroblast cells were grown in lethally irradiated 3T3 cells. Boyce et al. like the present claims call for the use of lethally irradiated 3T3 cells. Given that both Boyce et al. and the present invention grow epidermal cells on lethally irradiated 3T3 cells, the extracellular matrix recited in Applicant's claims would be inherent to the method of Boyce et al. See column 2, lines 43-47. When Applicant claims a property, which is inherently present in the prior art, the property does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to repeat the step of killing fibroblast cells in the present method because Boyce et al. teach killing fibroblast cells to culture keratinocytes and it is well within the ordinary skill in the art to repeat any steps as necessary. One of ordinary skill in the art would be motivated to repeat said step in order to confirm that the fibroblast cells are killed such that a culture consisting of epidermal cells is grown as taught by Boyce et al. The ordinary skilled artisan would reasonably expect that irradiation would kill the fibroblast cells during the second application because Boyce et al. teach that it kills cells. Applicant has argued that they are not certain "how one might irradiate cells, test how 'killed' they were, and then irradiate them some more until they were sufficiently 'killed'" The examiner has not asserted that one go through such a methodology in repeating the irradiation steps of the claimed method. Rather, the repetition of any number method steps is germane to the art to confirm success of a procedure or to assure elimination of undesired contaminants. Additionally, the open language of the present claims does not exclude additional steps or elements to the claims. See, e.g., *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495,501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997).

Furthermore, it would have been obvious to one of ordinary skill in the art to perform the claimed method in the same culture vessel. Indeed, Rheinwald et al. teach that irradiated 3T3 cells and keratinocytes are grown in the same culture vessel. See page 422 second column. One of skill in the art would have been motivated to leave the 3T3 cells in the initial growth vessel and inoculate the keratinocytes in that vessel for reasons including expediency, ease of use and even just saving resources. Because both Boyce et al. and Rheinwald et al. show that keratinocyte growth is supported by irradiated 3T3 cells one of skill in the art would reasonably expect that keratinocyte growth would be supported regardless of whether the same or a different culture vessel was used. It is applicant's burden to demonstrate unexpected results over the prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). In the instant case, there is no comparative data to the closest prior art for the evaluation of any possible the unexpected results over the same.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (703) 305-1999. The examiner can normally be reached on Monday through Friday 7:30 to 4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3388.

Konstantina Katcheves
May 19, 2003



JAMES KETTER
PRIMARY EXAMINER